

DEC 16 2009

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## 5. 510(k) Summary

### 5.1 Preparation Date 02 October 2009

#### Submitted By

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#### Contact Person/ Prepared By

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### 5.2 Device Identification

**Trade Name** LouseBuster™  
**Common Name** Louse Eradication System  
**Classification Name** Lice Removal Kit §880.5960

### 5.3 Predicate Device(s)

LouseBuster (K083206)

### 5.5 Device Description

The LouseBuster (LB) is a portable, electrically powered, reusable, device that can be used to direct controlled, heated airflow to kill Lice on the hair and scalp of patients with head lice infestations.

The device consists of an applicator, a flexible delivery hose, and a base unit comprising heating and air movement elements with associated safety monitoring and temperature control circuitry. The mechanical and electrical components of the device are protected in a molded, non-metallic housing. A detachable delivery hose provides a pathway for channeling the flowing, heated air created in the base unit to the single-use, disposable applicator. The single-use applicator is attached to the hose by the user before initiating LB treatment. During treatments, the applicator is manually positioned by the user to

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systematically direct heated air to kill or remove lice present in the scalp and hair roots of an infested individual.

#### **5.6 Intended Use**

The LouseBuster™ is intended for use to kill or remove lice and lice eggs in the head hair of adults and children 4 years of age and older.

#### **5.7 Comparisons and Conformance with Standards**

No design changes have been made to the device. From design and manufacturing standpoints, the subject LouseBuster device is identical to the cleared LouseBuster device.

#### **5.8 Conclusion**

The LouseBuster intended for non-prescription use is substantially equivalent to the predicate LouseBuster intended for prescription use, and is safe and effective for its intended use.



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room W-O66-0609  
Silver Spring, MD 20993-0002

DEC 16 2009

Larada Sciences, Incorporated  
C/o Phil Triolo, PhD, RAC  
Principal  
Phil Triolo And Associates LC  
148 South 1200 East  
Salt Lake City, Utah 84102

Re: K093144

Trade/Device Name: Larada Sciences LouseBuster™ Lice Eradication System  
Regulation Number: 21 CFR 880.5960  
Regulation Name: Lice Removal Kit  
Regulatory Class: I  
Product Code: LJL  
Dated: October 2, 2009  
Received: October 5, 2009

Dear Dr. Triolo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

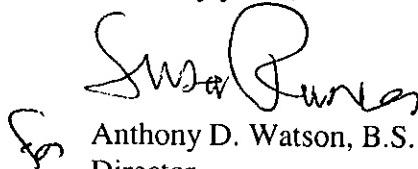
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to

<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address  
<http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.  
Director

Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

K093144

Larada Sciences,  
Inc.

Premarket Notification  
**LouseBuster™**

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## Indications for Use

510(k) Number (if known):

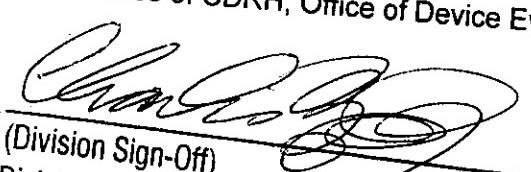
Device Name: **Larada Sciences LouseBuster™ Lice Eradication System**

Indications For Use: **The LouseBuster™ is intended for use to kill or remove lice and lice eggs in the head hair of adults and children 4 years of age and older.**

Prescription Use \_\_\_\_\_ AND/OR  
CFR 801 Subpart D) (21 CFR 801 Subpart C) Over-The-Counter Use  (Part 21)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF  
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

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